

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Originally numbered claims 1 and 45 (re-numbered claims 1 and 34, respectively) have been amended as follows:

1. (Currently Amended) An oral pharmaceutical composition comprising an active peptide agent that has an amide group at its C-terminus, and is not found in nature with an amide group at its C-terminus, wherein said active peptide agent is a human parathyroid hormone analog having the first 34 amino acids of human parathyroid hormone wherein the 34th amino acid is amidated at its C-terminus, said composition further comprising an absorption enhancer effective to promote bioavailability of said active peptide agent, or a pharmaceutically acceptable pH-lowering agent that is present in said pharmaceutical composition in a quantity which, if said composition were added to ten milliliters of 0.1M aqueous sodium bicarbonate solution, would be sufficient to lower the pH of said solution to no higher than 5.5.

45. (Currently Amended) A method for modifying a physiologically active peptide to increase its oral bioavailability, while substantially maintaining its physiological activity, said method comprising:

(A) amidating a physiologically active peptide that is not naturally amidated at its C-terminus at said C-terminus, wherein said amidated peptide is human parathyroid hormone analog PTH1-34-NH₂; and

(B) orally administering said amidated peptide in combination with (i) at least one absorption enhancer effective to promote bioavailability of said amidated peptide, or (ii) a pH-lowering agent that is present in said a pharmaceutical composition comprising said amidated peptide in a quantity which, if said composition were added to ten milliliters of 0.1M aqueous sodium bicarbonate solution, would be sufficient to lower the pH of said solution to no higher than 5.5.

Originally numbered claims 37, 39, 40, 41, 42, 55, 57, 58, 59, and 60 have been canceled.

Authorization for this examiner's amendment was given in a telephone interview with Attorney Danielle T. Abramson on November 2, 2011.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:00 A.M. to 5:30 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Cecilia Tsang can be reached at (571) 272-0562. The fax number for formal communications to be entered into the record is (571) 273-8300; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey E. Russel/
Primary Examiner, Art Unit 1654

JRussel
November 8, 2011